

Docket No.: 066783-0142



PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant : Targan, Stephan R., et al.  
Appl. No. : 10/723,164  
Filed : November 26, 2003  
Title : METHODS OF ASSESSING  
CROHN'S DISEASE PATIENT  
PHENOTYPE BY I2, OMPC AND  
ASCA SEROLOGIC RESPONSE  
Grp./A.U. : 1644  
Examiner: : Unassigned

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Sarah Nunez

**INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In accordance with the provisions of 37 C.F.R. 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the documents listed on the attached form PTO-1449. It is respectfully requested that the documents be expressly considered during the prosecution of this application, and that the documents be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No certification or fee is required.

Inventors: Targan et al.  
Serial No. 10/723,164  
Filed: November 26, 2003

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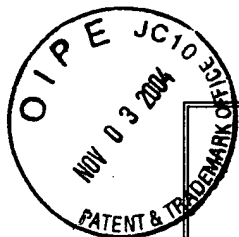
Respectfully submitted,

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**Date: November 3, 2004**  
SDO 20897-1.066783.0142



<b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  (PTO-1449)	ATTY. DOCKET NO. <b>066783-0142</b>	SERIAL NO. <b>10/723,164</b>
	APPLICANT <b>Targan et al.</b>	
	FILING DATE <b>November 26, 2003</b>	GROUP: <b>1644</b> CONFIRMATION NO.: <b>8299</b>

U.S. PATENT DOCUMENTS								
EXAMINER'S INITIALS	CITE NO.	Document Number Number-Kind Code <sup>2</sup> (if known)		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
	1.	US	6,309,643	10/30/01	Braun et al.			
FOREIGN PATENT DOCUMENTS								
EXAMINER'S INITIALS	CITE NO.	Foreign Patent Document Country Codes-Number 4 -Kind Codes (if known)		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Figures Appear	Translation	
	2.	WO 00/66067		11/9/00	Braun et al.		Yes	No
	3.	WO 01/89361		5/17/01	Targan et al.			
OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)								
EXAMINER'S INITIALS	CITE NO.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.						
	4.	ABREAU et al., "Mutations in <i>NOD2</i> Are Associated With Fibrostenosing Disease in Patients with Crohn's Disease," <u>Gastroenterology</u> 123:679-688 (2002).						
	5.	AHMAD et al., "The Molecular Classification of the Clinical Manifestations of Crohn's Disease," <u>Gastroenterology</u> 122:854-866 (2002).						
	6.	ANNESE et al., "Familial expression of anti-Saccharomyces cerevisiae Mannan antibodies in Crohn's disease and ulcerative colitis: a GISC study," <u>Am. J. Gastroenterology</u> 96: 2407-2412 (2001).						
EXAMINER				DATE CONSIDERED				

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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7.	CUTHBERT et al., "The contribution of NOD2 gene mutations to the risk and site of disease in inflammatory bowel disease," <u>Gastroenterology</u> 122: 867-874 (2002).	
8.	DALWADI et al., "The Crohn's disease-associated bacterial protein I2 is a novel enteric T cell superantigen," <u>Immunity</u> 15:149-158 (2001).	
9.	ELSON CO, "Genes, microbes, and T cells—new therapeutic targets in Crohn's disease," <u>New Engl. J. Med</u> 346:614-616 (2002).	
10.	GASCHE et al., "A simple classification of Crohn's disease: report of the Working Party for the World Congresses of Gastroenterology, Vienna 1998," <u>Inflamm. Bowel Dis.</u> 6:8-15 (2000).	
11.	GREENSTEIN et al., "Perforating and non-perforating indications for repeated operations in Crohn's disease: evidence for two clinical forms," <u>Gut</u> 29:588-592 (1988).	
12.	HAMPE et al., "Association between insertion mutation in <i>NOD2</i> gene and Crohn's disease in German and British populations," <u>Lancet</u> 357:1925-1928 (2001).	
13.	HELIO et al., "CARD15/NOD2 gene variants are associated with familially occurring and complicated forms of Crohn's disease," <u>Gut</u> 52:558-562 (2003).	
14.	HUGOT et al., "Mapping of a susceptibility locus for Crohn's Disease on chromosome 16," <u>Nature</u> 379:821-823 (1996).	
15.	HUGOT et al., "Association of NOD2 leucine-rich repeat variants with susceptibility to Crohn's disease," <u>Nature</u> 411:599-603 (2001).	

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16.	INOHARA et al., "Host recognition of bacterial muramyl dipeptide mediated through NOD2. Implications for Crohn's disease," <u>J. Biol. Chem.</u> 278:5509-5512 (2003).	
17.	LANDERS et al., "Selected Loss of Tolerance Evidenced by Crohn's Disease-Associated Immune Responses to Auto- and Microbial Antigens," <u>Gastroenterology</u> 123:689-699 (2002).	
18.	LESAGE et al., " <i>CARD15/NOD2</i> Mutational Analysis and Genotype-Phenotype Correlation in 612 Patients with Inflammatory Bowel Disease," <u>Am. J. Hum. Genet.</u> 70:845-857 (2002).	
19.	LOUIS et al., "Early development of stricturing or penetrating pattern in Crohn's disease is influenced by disease location, number of flares, and smoking but not by NOD2/CARD15 genotype," <u>Gut</u> 52:552-557 (2003).	
20.	MOW et al., "Antibodies Against the Crohn's disease (CD)-associated bacterial sequence I2 (anti-I2) are an independent marker of fibrostenosing CD," title only, published on DDW.org website as of 2/21/03;	
21.	MOW et al., "Antibodies Against the Crohn's disease (CD)-associated bacterial sequence I2 (anti-I2) are an independent marker of fibrostenosing CD," <u>Gastroenterology</u> 124(4 Supple. 1):A2 Abstract #26 (April 2003).	
22.	OGURA et al., "A frameshift mutation in <i>NOD2</i> associated with susceptibility to Crohn's Disease," <u>Nature</u> 411:603-606 (2001).	
23.	QUINTON et al., "Anti-Saccharomyces cerevisiae mannan antibodies combined with antineutrophil cytoplasmic autoantibodies in inflammatory bowel disease: prevalence and diagnostic role," <u>Gut</u> 42:788-791 (1998).	

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24.	RADLMAYR, et al., "The c-insertion mutation of the NOD2 gene is associated with fistulizing and fibrostenotic phenotypes in Crohn's disease," <u>Gastroenterology</u> 122:2091-2092 (2002).	
25.	SAXON et al., "A distinct subset of antineutrophil cytoplasmic antibodies is associated with inflammatory bowel disease," <u>J. Allergy Clin. Immunol.</u> 86:202-210 (1990).	
26.	SENDID et al., "Specific antibody response to oligomannosidic epitopes in Crohn's disease," <u>Clin. Diagn. Lab Immunol.</u> 3:219-226 (1996).	
27.	SUGIMURA et al., "A novel NOD2/CARD15 haplotype conferring risk for Crohn disease in Ashkenazi Jews," <u>Am. J. Hum. Genet.</u> 72:509-518 (2003).	
28.	SUTTON et al., "Identification of a novel bacterial sequence associated with Crohn's disease," <u>Gastroenterology</u> 119:23-31 (2000).	
29.	SUTTON et al., "Familial expression of anti-Saccharomyces cerevisiae mannan antibodies in affected and unaffected relatives of patents with Crohn's disease," <u>Gut</u> 46: 58-63 (2000).	
30.	VASILIAUSKAS et al., "Marker antibody expression stratifies Crohn's disease into immunologically homogeneous subgroups with distinct clinical characteristics," <u>Gut</u> 47:487-496 (2000).	
31.	VASILIAUSKAS et al., "Perinuclear antineutrophil cytoplasmic antibodies in patients with Crohn's disease define a clinical subgroup," <u>Gastroenterology</u> 110: 1810-1819 (1996).	
32.	WEI et al., " <i>Pseudomonas fluorescens</i> encodes the Crohn's disease-associated I2 sequence and T-cell superantigen," <u>Infect. Immun.</u> 70:6567-6575 (2002).	

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